REMARKS

Objection Under 35 U.S.C. § 132(a)

The Office objects under 35 U.S.C. § 132(a) that new matter has been introduced into the disclosure of the invention. Specifically, the Office objects to the following phrases: "determining an oxybutynin plasma concentration in the patient in said fasted state," "determining an oxybutynin plasma concentration in the patient in said fed state," and "comparing an oxybutynin plasma concentration observed in said fasted state with an oxybutynin plasma concentration observed in a fed state." Applicants traverse this objection.

Applicants point out that the various steps recited by the office as new matter are actually found at various points in the specification, particularly at page 33, lines 20 et seq. and Figure 6. It is manifestly clear that Applicants determined oxybutynin plasma concentrations in fed and fasted patients; that is the data that is presented in Figure 6. The comparison between the oxybutynin plasma concentrations is made, among other places, in the specification at page 33, wherein Applicants state that the plasma concentration of oxybutynin in fed and fasted patients is similar when oxybutynin is administered according to the invention.

The steps of determining and comparing were performed by Applicants prior to the filing date of the present application. The language and data contained in the disclosure as originally filed supports Applicants' contentions. Accordingly, no new matter has been added. Applicants therefore request withdrawal of the new matter objection under 35 U.S.C. § 132(a).

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 15-50 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Office asserts that the specification does not provide enablement for administering any dosage form as claimed in claims 1[5]-50. OA at 3. Applicants traverse this rejection.

Applicants note that the Office has the initial burden when making a rejection for lack of enablement to establish a reasonable basis to question the enablement provided. MPEP § 2164.04. This can be done by making scientific findings of fact, supported by the evidence. Id. The Office has not so introduced any evidence suggesting that there was uncertainty as to enablement. The Office has merely asserted that the specification discloses a sustained release dosage form with a specific structure. OA at 3.

In fact, Applicants' claims are directed to a release rate that provides the recited benefits with respect to fed-fasted performance. These release rates are specified, among other locations, in Examples 5, 13, and 14. It would have been within the skill of one of skill in the art to utilize these teachings, and the teachings of the disclosure generally, to arrive at other embodiments that would be covered by the claims.

Absent any evidence relating to enablement, and in light of the teaching of the disclosure, the Office has no basis for any finding of fact that supports its convention of non-enablement. Without such fact finding, the Office has not made out a proper prima facie case of non-enablement. Accordingly, Applicants request withdrawal of the rejection of claims 15-50 under 35 U.S.C. § 112, first paragraph, for lack of enablement.

Rejection Under 35 U.S.C. § 103(a): Guittard in view of Oshlack

Claims 15-50 are rejected under 35 U.S.C. § 103(a) as obvious over Guittard et al. US Patent 5,912,268 ("Guittard") in view of Oshlack US Patent 5,965,161 ("Oshlack"). Applicants traverse this rejection.

The Office notes that Guittard does not teach a dosage form that would exhibit the same plasma concentration in a fed state and a fasted state.

The Office then argues that the combination of Guittard with Oshlack discloses the invention. In fact, that is not the case. Independent claims 15, 24, 33, and 42 all recite an oxybutynin release rate that accomplishes a desired outcome. Applicants take the position that it is this release rate teaching that accomplishes the recited similarity of performance under fed and fasted conditions.

Oshlack's teaching, as cited by the Office, is maintaining drug plasma concentrations within the therapeutic range but below toxic levels for a broad genus of drugs. OA at 5. This is not the same as teaching or suggesting the release rate recited by Applicants. It is possible to achieve release rates of oxybutynin from controlled release dosage forms that are within a therapeutic range but below toxic levels, and yet are not similar under fed and fasted conditions. Specification at page 33, line 28 to page 34, line 15.

The Office has not shown that the combination of Guittard and Oshlack teaches or suggests all of the claim limitations. To establish prima facie obviousness requires that all of the claim limitations be found in the prior art. MPEP § 2143.03. Accordingly, the Office has not made out a prima facie case of obviousness with respect to claims 15-50 over Guittard in view of Oshlack. Applicants therefore request withdrawal of the rejection under 35 U.S.C. § 103(a) over Guittard in view of Oshlack.

Rejection Under 35 U.S.C. § 103(a): Guittard in view of Morella

Claims 15-50 are rejected under 35 U.S.C. § 103(a) as obvious over Guittard et al. US Patent 5,912,268 ("Guittard") in view of Morella et al., US Patent 5,378,474 ("Morella"). Applicants traverse this rejection.

The Office notes that Guittard does not teach a dosage form that would exhibit the same plasma concentration in a fed state and a fasted state.

The Office then argues that the combination of Guittard with Morella discloses the invention. In fact, that is not the case. Independent claims 15, 24, 33, and 42 all recite an oxybutynin release rate that accomplishes a desired outcome. Applicants take the position that it is this release rate teaching that accomplishes the recited similarity of performance under fed and fasted conditions.

Applicants point out that the release rate as taught by Morella varies significantly as the dosage form of Morella passes through the gastrointestinal tract. For instance, at Column 8, lines 34-37 and 46-51, and in the Abstract, Morella teaches a faster release rate in the upper GI and a slower release rate in the lower GI. Morella, in other words, teaches a varying release rate.

Guittard, at Columns 13 and 14, speculates that the absorption of oxybutynin may differ at different points in the gastrointestinal tract possibly due to presystemic metabolism. Assuming this to be true, the combination of Guittard and Morella would produce a dosage form that varies release rate as a function of position within the GI tract coupled with varying absorption of oxybutynin as a function of position within the GI tract.

The Office has not produced any reasoning or data that explains how one of skill in the art could have reasonably expected to succeed in achieving a dosage form unaffected by food using the combined teachings of Guittard and Morella. In fact, to one of ordinary skill in the art, the disclosure of Guittard would have taught away from expecting success by using the dosage form of Morella. One of ordinary skill in the art would have expected that changing both absorption **and** release rate as a function of position within the GI tract almost guaranteed a food effect in a dosage form.

There is no reasonable expectation that the combination of Guittard and Morella would have successfully resulted in the recited release rate of the present invention. A reasonable expectation of success is required for a prima facie case of obviousness. MPEP §§ 2142, 2143.02. Accordingly, the Office has not made out a prima facie case of obviousness with respect to claims 15-50 over Guittard in view of Morella. Applicants therefore request withdrawal of the rejection under 35 U.S.C. § 103(a) over Guittard in view of Morella.

CONCLUSION

The examination and passage to allowance of the pending claims are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicant invites the Examiner to contact the undersigned at (650) 564-2498 to clarify any unresolved issues raised by this response.

Applicants believe that no fee is due with this submission. If it is determined that underpayment or overpayment has been made, the Director is authorized to debit or credit Deposit Account 10-0750, respectively.

Respectfully submitted,

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